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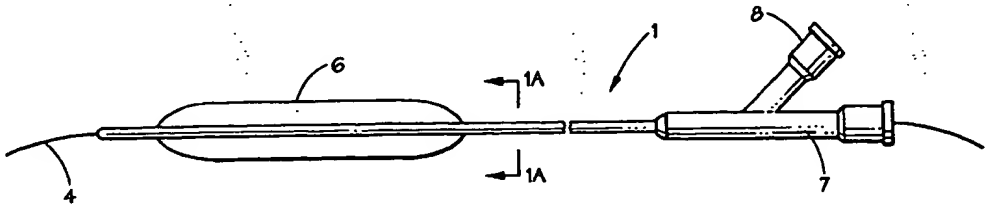

(57) Abstract: A device for arteriographies and angiographies includes a catheter having an inflatable, elastimeric, and soft diagnosis balloon, which may be inflated with a contrast media, with the diagnosis balloon having an inflated shape which copies, but does not deform, the inner surface of a narrowed portion of an artery. The narrowed portion of the artery may be angiographed or arteriographed while the diagnosis balloon is inflated and copies the inner surface of the narrowed portion of the artery.

WO 02/22199 A2

METHOD AND DEVICE TO DO ARTERIOGRAPHIES AND ANGIOGRAPHIES WITH A BALLON WITHOUT INJECTING CONTRAST MEDIA IN THE VESSEL LUMEN

RELATED APPLICATION

This application is a continuation-in-part application of Application Serial No. 08/751,909, filed November 18, 1996, entitled "Device and Method to do Arteriographies and Angioplasties With a Balloon and Without Injecting a Contrast Media in the Vessel Lumen", now U.S. Patent No. 6,117,124.

FIELD OF THE INVENTION

The present invention relates to the angioplasty techniques as well as to tests on arteries having narrowed or occluded portions and more particularly to a device and a method to do arteriographies and angioplasties avoiding the injection of a contrasting medium in the vessel lumen.

DESCRIPTION OF THE RELATED ART

The use of techniques availing of a catheter that includes a balloon to repair artery stenoses are known in the prior art. Stenosis and artery blockage decrease the nourishing flow that reaches the tissues irrigated by the affected artery. Tissue disorder caused by a decrease in irrigation may vary from necrosis of tissue to functional disorders caused by the decrease in the said flow. Sometimes, secondary arteries balance the blockage of the main artery. Whenever the narrowing of the artery is treated due to the consequences of flow decrease, it should be decided whether to resort to surgery or to the dilation of the artery by making use of a balloon.

SUMMARY OF THE INVENTION

Therefore, it is an object of the present invention to provide a new device and a method to do arteriographies, allowing for the simultaneous angioplasties as by inserting a catheter and a balloon capable of copying the narrowed portion of the artery under study and providing for the contrast required to view the artery, by utilizing a contrasting medium which is circumscribed within the balloon and which is not in relationship with the patient's tissue. Therefore, it is an object of the present

invention to provide a device to do arteriographies and angioplasties of the type that uses a catheter wherein at least two passages are formed, first and second passage, the first passage being utilized to run a guide wire, and which includes at least a first inflatable, elastomeric and soft balloon that is in relationship with the second passage. The latter configures a duct whereby an arteriographic contrasting medium is introduced.

It is a further object of the present invention to provide a method to do arteriographies and angioplasties, which method employs the device described above and comprises the following steps: an artery is punctured remote of the stenoses or occlusion, an introducer is inserted thus allowing for the passage of a catheter, at least one of the balloons is moved until the narrowed portion of the artery is crossed over, the balloon is placed all along the artery under study, the balloon is filled with an arteriographic contrast substance at a very low pressure without deforming the narrowing, the balloon is kept inflated, angiography tests are done and finally the balloon is deflated.

BRIEF DESCRIPTION OF THE DRAWINGS

For further clarification and a better understanding of the object of the present invention, numerous figures have been drawn depicting some of the preferred embodiments of the present invention for purposes of illustration only, where:

FIG. 1 is a side view including a detail of the cross-sectional view of a catheter in accordance with the device of the present invention;

FIG. 1A is a cross-sectional view taken along line 1A-1A of FIG. 1;

FIG. 2 is a view similar to FIG. 1 of another embodiment of the device of the present invention;

FIG. 2A is a cross-sectional view taken along line 2A-2A of FIG. 2;

FIG. 3 is a view similar to FIG. 1 of another embodiment of the device of the present invention;

FIG. 3A is a cross-sectional view taken along line 3A-3A of FIG. 3;

FIG. 4 is a view similar to FIG. 1 of another embodiment of the device of the present invention;

FIG. 4A is a cross-sectional view taken along line 4A-4A of FIG. 4; and,

FIGS. 5 to 8 show the stages of a preferred embodiment of the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

As shown in FIG. 1, a catheter 1 is provided, the cross-sectional view of which in detail shows a first passage 2 that allows a guide wire 4 to run along the shaft 5 of the catheter, also providing a second passage 3 whereby the first elastomeric, thin walled and resistant, low profile diagnosis balloon 6 is inflated. The material used for the said balloon may be latex, silicone, polyurethane or any other appropriate and elastomeric material whatsoever. The guide wire 4 as well as the balloon 6 may be operated via operation means 7 and 8. Pursuant to the present invention, the balloon 6 is carried up to the narrowed portion of the artery, as detailed when referring to FIGS. 5 to 8, and filled with an appropriate contrast media, such as a radiopaque substance. The balloon has a very thin but resistant wall, which, upon inflation, takes exactly the same form of the artery inner surface (luminogram) without deforming same. The balloon 6 shall have the length required to view the desired portion of the artery. Amongst the main features, the balloon may be inflated at a very low pressure thus not altering, as stated above, the contour of the artery under study. This device allows a guide wire to run along the artery lumen. Owing to the fact that the balloon has a very low profile, same allows for the introduction thereof in the narrowed or occluded portion of the artery, which portion is crossed over by the guide wire. The balloon 6 may be inflated at pressure of 1 to 3 atmospheres, and preferably at a pressure of approximately 2 atmospheres.

Diagnosis balloon 6, as previously described, can be formed of a variety of elastomeric materials such as silicone, latex, or polyurethane. The elastomeric materials from which the diagnosis balloon 6 may be made are preferably ultra compliant, whereby they are capable of stretching, or expanding, up to more than 500% from their relaxed, or unstretched, state. These diagnosis balloons 6, when inflated, as previously discussed, are capable of copying, or conforming to, the shape of the vessel, or artery, interior, without expanding or distending the artery, or vessel, itself. Preferably, the material from which the diagnosis balloon is made, has an elongation property (percentage), before breaking, of from approximately 500% to

2,000% and preferably within the range of from approximately 800% to 1200%. Examples of a suitable material for the manufacture of the diagnosis balloons are silicone elastomers, such as models MED-4120 and MED-4020, of NuSil Technology of Carpinteria, California. These elastomers have elongation properties of 1100% and 1000%.

Once the luminogram is obtained by injecting the contrasting medium in the balloon, dilation of the narrowing may then proceed by using a second expanding balloon located upon the catheter that carries the diagnosis balloon, as shown in the three embodiments of the present invention illustrated in FIGS. 2, 3, and 4.

The catheter 1a in FIG. 2 has a first passage 9 for the guide wire 4a to run, a second passage 10 that allows inflation of the diagnosis balloon 6a, similar to balloon 6 in FIG. 1 and a third passage 11 permitting the expansion of the angioplasty balloon 12, located behind the diagnosis balloon 6a.

Catheter 1b in FIG. 3 includes a first passage 13 for the guide wire 4b to run and a second passage 14 which allows the diagnosis balloon 6b to be inflated, which balloon is similar to balloons 6 and 6a; said catheter also includes a container that shelters a therapeutic or angioplasty balloon 12′. The diagnosis balloon 6b carries the therapeutic balloon 12′ within its lumen. The therapeutic balloon 12′ runs on the wire 4b and provides consistency to the diagnosis balloon 6b.

Catheter 1c illustrated in FIG. 4 is similar to the one depicted in FIG. 3, but the therapeutic balloon 12′′ is fixed within the diagnosis balloon 6c anchored to the shaft of the catheter 1c, thus a third passage 15 is provided for such purpose.

The second balloons 12, 12′ and 12′′ of the different embodiments of the present invention differ from diagnosis balloons 6 to 6c in that the former are not elastomeric for the purpose of achieving a great radial force allowing for the dilation of the narrowed artery. The angioplasty balloon shall have a low profile and shall be inflated through an independent passage of the catheter, as illustrated in the case of the three passages of the pertinent embodiments.

In the event the angioplasty balloon is sheltered inside the diagnosis balloon, the latter shall enclose a tiny catheter which houses in turn, a guide wire and said catheter shall act as a rail on which the second balloon is run, and which shall be

suitably located to proceed to the dilation of the artery narrowing. The second balloon may be fixedly anchored and shall move jointly with the elastomeric balloon so as to be placed in the right location to dilate the narrowed portion of the artery.

In accordance with another aspect of the present invention, diagnosis balloons 6, 6a, 6b, and/or 6c, may be coated or doped with a radiopaque substance, such as barium, gold, platinum, or silver. Alternatively, such a radiopaque substance may be mixed into the elastomeric material from which the diagnosis balloons are made. The diagnosis balloons would thus be radiopaque, whereby the diagnosis balloon would not need to be expanded by the introduction of a contrast substance, but could rather be expanded with a non-radiopaque fluid, such as non-toxic gases, such as carbon dioxide, or by liquids such as water or other non-toxic liquid mixtures. A radiopaque diagnosis balloon could be utilized in conjunction with an angioplasty balloon such as angioplasty balloons 12, 12′ and/or 12′′, as previously described. The foregoing described radiopaque diagnosis balloons, whether used alone, or in conjunction with an angioplasty balloon, may be inflated to conform to vessel, or artery, irregularities and narrowing. It is believed that a radiopaque diagnosis balloon will be useful in imaging ostial lesions, where a large vessel has branches, and where stenosis can occur at the junction of two vessels. Again, as with a diagnosis balloon filled with a contrast material, there is a significant clinical advantage since toxic radiopaque contrast media need not come into contact with living tissue.

As regards another aspect of the present invention, a method is illustrated in FIGS. 5 to 8, which method comprises the following steps: the artery is punctured and a guide wire is introduced which crosses over narrowing or occlusion "E", as illustrated in FIG. 5. This step is similar to any other angiographic procedure which may include angioplasty or not. Subsequently, an introducer means of a suitable size is placed to allow the introduction of a diagnosis-therapeutic catheter.

The device is moved forward until the narrowing "E" is crossed over, placing the diagnosis balloon of the present invention all along the artery under study, as illustrated in FIG. 6. The diagnosis balloon is filled with a contrasting substance at a very low pressure and the balloon is kept dilated. The angiographic tests are accurately done and the catheter is placed in the right angle and location so as to

achieve a better view of the narrowed portion of the artery.

Once the diagnosis is made, the elastomeric balloon is deflated and the angioplasty balloon 12 is placed at the narrowing "E" level. Then, same is inflated for the purpose of dilating the injured portion of the artery. The angioplasty balloon is deflated and the diagnosis elastomeric balloon is affixed in the right position, repeating the diagnosis steps for the purpose of confirming the effectiveness of the artery dilation attained. Should dilation be suitable, the proceeding shall be deemed to be finished; should dilation fail to be suitable, the proceeding shall be repeated. If the correct results are not obtained, a balloon having a different diameter may be affixed avoiding the initial system; a "stent" may alternatively be attached. For the purpose of anchoring same, the very same non-elastomeric balloon that comprises the device may be used or else, another balloon with different features may be employed.

If the diagnosis balloons 6, 6a, 6b, and/or 6c have been made radiopaque, as previously described, the foregoing described method may also be conducted in the same manner, except that it would not be necessary to fill the radiopaque diagnosis balloon with a contrast substance. Of course, if desired, the radiopaque balloon could be filled with a contrast substance at a very low pressure.

According to the method and the device of the present invention, many advantages are gained, for instance: no contrasting medium needs to be injected in the lumen of the vessel, thus avoiding pain, possible allergy development and renal damage caused by the contrasting medium. Carbon dioxide may be alternatively used to inflate the balloon, thus obtaining the digital image by contrast reduction and not by contrast increase, as in the case of radiopaque substances. The advantage of having carbon dioxide inside and not outside the balloon lies in that a permanent image of the artery lumen is obtained, and several incidences may also be achieved with no need for further gas inoculations. Whether by changing the location of the whole device or of the non-elastomeric balloon, the angioplasty may be done without changing the device and an x-ray check-up may be done simultaneously as by inflating the elastomeric balloon again in order to confirm the effectiveness of the dilation as regards reduction of artery narrowing. This procedure proves to be cost efficient since the amount of contrasting substance injected as well as the time

consumed are reduced.

As the contrast media is not injected directly into the artery, substances utilized do not need to be non-ionic. Both quality and volume of contrast media can be a source of decreasing costs in addition to the advantages enumerated in relation to decreasing risks to the patient.

I claim:

1. A device for doing an arteriography in a narrowed portion of an artery, the artery having an inner surface, comprising:
a catheter having an inflatable, elastomeric diagnosis balloon, and a first
passage in fluid communication with the diagnosis balloon;
the diagnosis balloon being formed of an ultra compliant material having
an elongation property of between approximately 500% to 2000%;
the first passage being adapted to inflate the diagnosis balloon with a contrast
media, the contrast media being circumscribed within the diagnosis balloon and not in contact with the inner surface of the artery;
the diagnosis balloon having a first uninflated shape for delivery of the diagnosis balloon to a location within, and along, the narrowed portion of the artery; and
the diagnosis balloon having a second inflated shape, after being inflated with
the contrast media, the second inflated shape copying, and not deforming, the inner surface of the artery in the narrowed portion of the artery, whereby the diagnosis balloon and the narrowed portion of the artery may be arteriographed while the diagnosis balloon is in the second inflated shape.

2. The device of claim 1, including a second passage in the catheter for passage of a guide wire therethrough.

3. The device of claim 1, including an angioplasty balloon located on the catheter for dilating the narrowed portion of the artery.

4. The device of claim 3, wherein the diagnosis balloon is disposed toward a distal end of the catheter, and the angioplasty balloon is

disposed adjacent the diagnosis balloon.

5. The device of claim 4, wherein the angioplasty balloon is disposed inside the diagnosis balloon.

6. The device of claim 1, wherein the elongation property of the material forming the diagnosis balloon is between approximately 800% and 1200%.

7. The device of claim 1, wherein the material forming the diagnosis balloon is a silicone elastomer having an elongation property of between approximately 1000% to 1100%.

8. A device for doing an angiography in a narrowed portion of an vessel, the vessel having an inner surface, comprising:

a catheter having an inflatable, elastomeric diagnosis balloon, and a first

passage in fluid communication with the diagnosis balloon;

the diagnosis balloon being formed of an ultra compliant material having

an elongation property of between approximately 500% to 2000%;

the first passage being adapted to inflate the diagnosis balloon with

a contrast media, the contrast media being circumscribed within the diagnosis balloon and not in contact with the inner surface of the vessel;

the diagnosis balloon having a first uninflated shape for delivery of the

diagnosis balloon to a location within, and along, the narrowed portion of the vessel; and

the diagnosis balloon having a second inflated shape, after being inflated with

the contrast media, the second inflated shape copying, and not deforming, the inner surface of the vessel in the

narrowed portion of the vessel, whereby the diagnosis balloon and the narrowed portion of the vessel may be angiographed while the diagnosis balloon is in the second inflated shape.

9. The device of claim 8, including a second passage in the catheter for passage of a guide wire therethrough.

10. The device of claim 8, including an angioplasty balloon located on the catheter for dilating the narrowed portion of the vessel.

11. The device of claim 10, wherein the diagnosis balloon is disposed toward a distal end of the catheter, and the angioplasty balloon is disposed adjacent the diagnosis balloon.

12. The device of claim 11, wherein the angioplasty balloon is disposed inside the diagnosis balloon.

13. The device of claim 8, wherein the elongation property of the material forming the diagnosis balloon is between approximately 800% and 1200%.

14. The device of claim 8, wherein the material forming the diagnosis balloon is a silicone elastomer having an elongation property of between approximately 1000% to 1100%.

15. A method for doing arteriographies in a portion of an artery having an inner surface, comprising the steps of:

providing an expandable, elastomeric diagnosis balloon upon a catheter, the

diagnosis balloon having an outer surface, and being formed of an ultra compliant material having an elongation property of between approximately 500% to 2000%;

introducing the diagnosis balloon into the portion of the artery to be arteriographed;

filling the diagnosis balloon with a contrast medium to inflate the diagnosis balloon until the outer surface of the

diagnosis balloon conforms to the inner surface of the portion of the artery to be arteriographed, without deforming the inner surface of the portion of the artery to be arteriographed; and

imaging the inflated diagnosis balloon and the portion of the artery to the arteriographed.

16. The method of claim 15, including the steps of deflating the diagnosis balloon and removing the diagnosis balloon from the artery.

17. The method of claim 15, including the step of inflating the diagnosis balloon at a low pressure.

18. The method of claim 15, including the step of utilizing a radiopaque substance as the contrast medium.

19. The method of claim 15, including the step of utilizing a radiolucent substance as the contrast medium.

20. The method of claim 19, wherein the contrast medium is carbon dioxide.

21. The method of claim 15, including the steps of:

providing an angioplasty balloon upon the catheter; and

after the diagnosis balloon and the portion of the artery to be arteriographed are imaged, inflating the angioplasty balloon to dilate the portion of the artery which was imaged.

22. The method of claim 21, including the step of deflating the angioplasty balloon and removing the angioplasty balloon from the artery.

23. The method of claim 22, including the steps of:

after the portion of the artery has been dilated, placing the diagnosis balloon within the portion of the artery which was dilated by the angioplasty balloon;

filling the diagnosis balloon with a contrast medium to inflate the diagnosis balloon

until the outer surface of the diagnosis balloon conforms to the inner surface of the portion of the artery which had been

dilated; and

imaging the diagnosis balloon and the portion of the artery which had been dilated.

24. The method of claim 21, including the step of providing the angioplasty balloon upon the catheter, by disposing the angioplasty balloon within the diagnosis balloon.

25. The method of claim 15, including the step of forming the diagnosis balloon from a material having an elongation property between approximately 800% and 1200%.

26. The method of claim 15, including the step of forming the diagnosis balloon from a silicone elastomer having an elongation property of between approximately 1000% to 1100%.

27. A method for doing angiographies in a portion of a vessel having an inner surface, comprising the steps of:

providing an expandable, elastomeric diagnosis balloon upon a catheter, the diagnosis balloon having an outer surface and being formed of an ultra compliant material having an elongation property of between approximately 500% to 2000%;

introducing the diagnosis balloon into the portion of the vessel to be angiographed;

filling the diagnosis balloon with a contrast medium to inflate the diagnosis balloon until the outer surface of the diagnosis balloon conforms to the inner surface of the portion of the vessel to be angiographed, without deforming the inner surface of the portion of the vessel to be angiographed; and

imaging the inflated diagnosis balloon and the portion of the vessel to the angiographed.

28. The method of claim 27, including the steps of deflating the diagnosis balloon and removing the diagnosis balloon from the artery.

29. The method of claim 27, including the step of inflating the diagnosis balloon at a low pressure.

30. The method of claim 27, including the step of utilizing a radiopaque substance as the contrast medium.

31. The method of claim 27, including the step of utilizing a radiolucent substance as the contrast medium.

32. The method of claim 31, wherein the contrast medium is carbon dioxide.

33. The method of claim 27, including the steps of:

providing an angioplasty balloon upon the catheter; and

after the diagnosis balloon and the portion of the vessel to be angiographed are imaged, inflating the angioplasty balloon to dilate the portion of the vessel which was imaged.

34. The method of claim 33, including the step of deflating the angioplasty balloon and removing the angioplasty balloon from the artery.

35. The method of claim 34, including the steps of:

after the portion of the vessel has been dilated, placing the diagnosis balloon within the portion of the vessel which was dilated by the angioplasty balloon;

filling the diagnosis balloon with a contrast medium to inflate the diagnosis balloon until the outer surface of the diagnosis balloon conforms to the inner surface of the portion of the vessel which had been dilated; and

imaging the diagnosis balloon and the portion of the vessel which had been dilated.

36. The method of claim 33, including the step of providing the angioplasty balloon upon the catheter, by disposing the angioplasty balloon within the diagnosis balloon.

37. The method of claim 27, including the step of forming the diagnosis balloon from a material having an elongation property between approximately 800% and 1200%.

38. The method of claim 27, including the step of forming the diagnosis

balloon from a silicone elastomer having an elongation property of between approximately 1000% to 1100%.

39. A method for doing arteriographies in a portion of an artery having an inner surface, comprising the steps of:

providing an expandable, radiopaque elastomeric diagnosis balloon upon a catheter, the radiopaque diagnosis balloon having an outer surface;

introducing the radiopaque diagnosis balloon into the portion of the artery to be arteriographed;

filling the radiopaque diagnosis balloon with a fluid to inflate the radiopaque diagnosis balloon until the outer surface of the radiopaque diagnosis balloon conforms to the inner surface of the portion of the artery to be arteriographed, without deforming the inner surface of the portion of the artery to be arteriographed; and

imaging the inflated radiopaque diagnosis balloon and the portion of the artery to be arteriographed.

40. The method of claim 39, including the steps of deflating the radiopaque diagnosis balloon and removing the radiopaque diagnosis balloon from the artery.

41. The method of claim 39, including the step of inflating the radiopaque diagnosis balloon at a low pressure.

42. The method of claim 39, including the step of utilizing a non-toxic gas as the fluid.

43. The method of claim 39, including the step of utilizing a non-toxic liquid as the fluid.

44. The method of claim 43, wherein the fluid is carbon dioxide.

45. The method of claim 39, including the steps of:

providing an angioplasty balloon upon the catheter; and

after the radiopaque diagnosis balloon and the portion of the artery to be arteriographed are imaged, inflating the angioplasty balloon to dilate the portion of the artery which was imaged.

46. The method of claim 45, including the step of deflating the angioplasty balloon and removing the angioplasty balloon from the artery.

47. The method of claim 46, including the steps of:

after the portion of the artery has been dilated, placing the radiopaque diagnosis balloon within the portion of the artery which was dilated by the angioplasty balloon;

filling the radiopaque diagnosis balloon with a fluid to inflate the radiopaque diagnosis balloon until the outer surface of the radiopaque diagnosis balloon conforms to the inner surface of the portion of the artery which had been dilated; and

imaging the radiopaque diagnosis balloon and the portion of the artery which had been dilated.

48. The method of claim 45, including the step of providing the angioplasty balloon upon the catheter, by disposing the angioplasty balloon within the radiopaque diagnosis balloon.

49. The method of claim 39, including the step of forming the radiopaque diagnosis balloon from an ultra compliant material having an elongation property of between approximately 500% to 2000%.

50. The method of claim 39, including the step of forming the radiopaque diagnosis balloon from an ultra compliant material having an elongation property of between approximately 800% to 1200%.

51. The method of claim 39, including the step of forming the radiopaque diagnosis balloon from a silicone elastomer having an elongation property of between approximately 1000% to 1100%.

52. A method for doing angiographies in a portion of a vessel having an inner surface, comprising the steps of:

providing an expandable, elastomeric radiopaque diagnosis balloon upon a catheter, the radiopaque diagnosis balloon having an outer surface;

introducing the radiopaque diagnosis balloon into the portion of the vessel to be angiographed;

filling the radiopaque diagnosis balloon with a fluid to inflate the

radiopaque diagnosis balloon until the outer surface of the radiopaque diagnosis balloon conforms to the inner surface of the portion of the vessel to be angiographed, without deforming the inner surface of the portion of the vessel to be angiographed; and

imaging the radiopaque inflated diagnosis balloon and the portion of the vessel to the angiographed.

53. The method of claim 52, including the steps of deflating the radiopaque diagnosis balloon and removing the radiopaque diagnosis balloon from the artery.

54. The method of claim 52, including the step of inflating the radiopaque diagnosis balloon at a low pressure.

55. The method of claim 52, including the step of utilizing a non-toxic gas as the fluid.

56. The method of claim 52, including the step of utilizing a non-toxic liquid as the fluid.

57. The method of claim 56, wherein the fluid is carbon dioxide.

58. The method of claim 52, including the steps of:

providing an angioplasty balloon upon the catheter; and

after the radiopaque diagnosis balloon and the portion of the vessel to be angiographed are imaged, inflating the angioplasty balloon to dilate the portion of the vessel which was imaged.

59. The method of claim 58, including the step of deflating the angioplasty balloon and removing the angioplasty balloon from the vessel.

60. The method of claim 59, including the steps of:

after the portion of the vessel has been dilated, placing the radiopaque diagnosis balloon within the portion of the vessel which was dilated by the angioplasty balloon;

filling the radiopaque diagnosis balloon with a fluid to inflate the radiopaque diagnosis balloon until the outer surface of the radiopaque diagnosis balloon conforms to the inner surface of

the portion of the vessel which had been dilated; and

imaging the radiopaque diagnosis balloon and the portion of the vessel which had been dilated.

61. The method of claim 58, including the step of providing the angioplasty balloon upon the catheter, by disposing the angioplasty balloon within the radiopaque diagnosis balloon.

62. The method of claim 52, including the step of forming the radiopaque diagnosis balloon from an ultra compliant material having an elongation property of between approximately 500% to 2000%.

63. The method of claim 52, including the step of forming the radiopaque diagnosis balloon from an ultra compliant material having an elongation property of between approximately 800% to 1200%.

64. The method of claim 52, including the step of forming the radiopaque diagnosis balloon from a silicone elastomer having an elongation property of between approximately 1000% to 1100%.

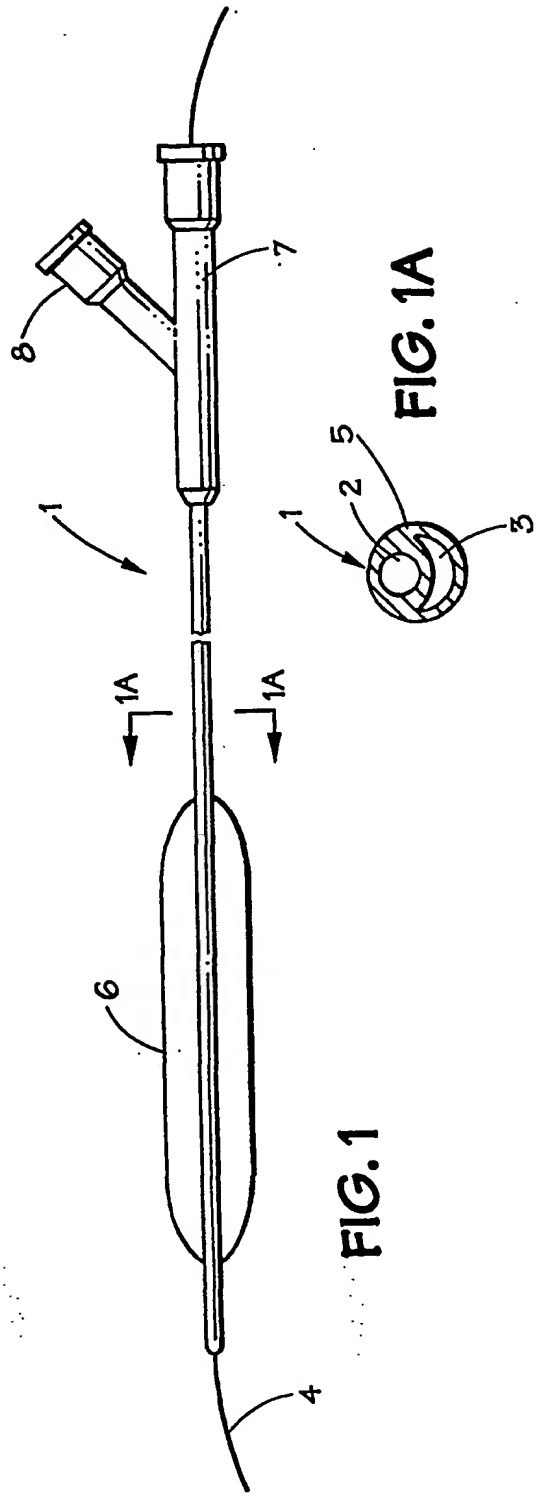

FIG. 1

FIG. 1A

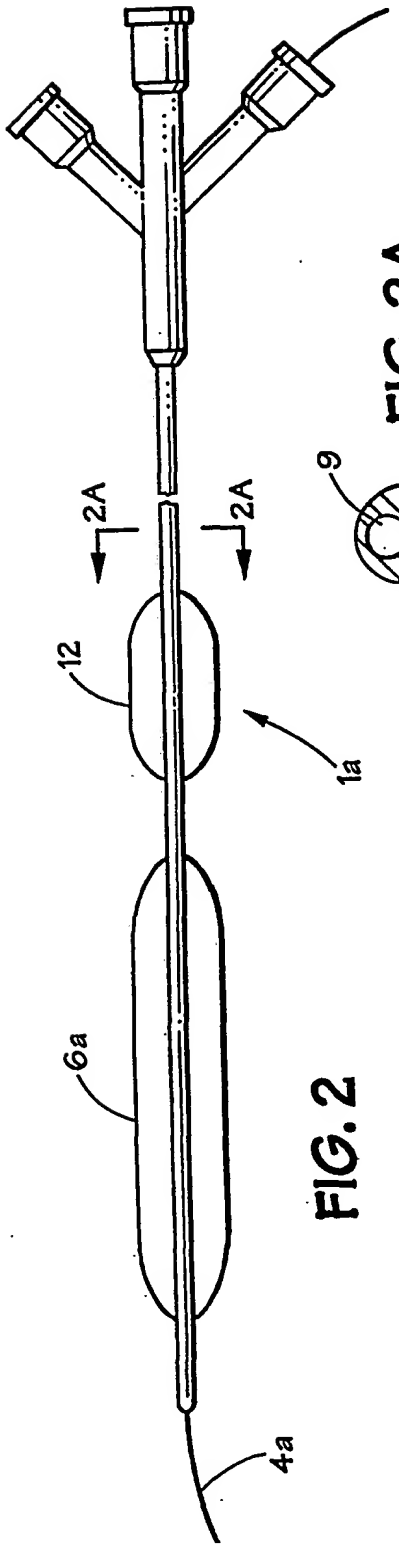

FIG. 2

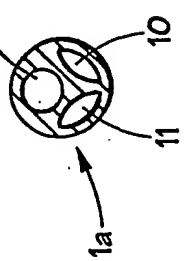

FIG. 2A

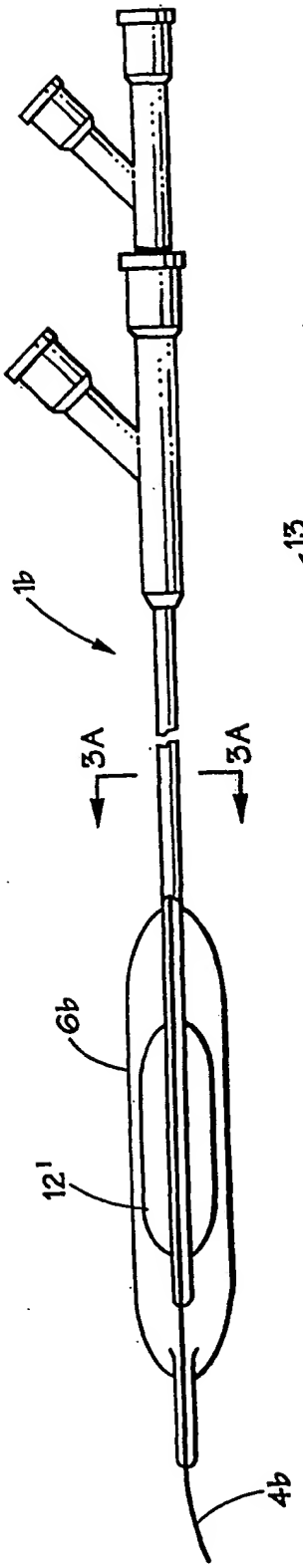

FIG. 3

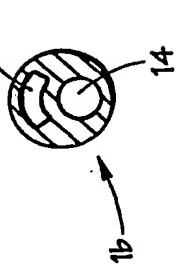

FIG. 3A

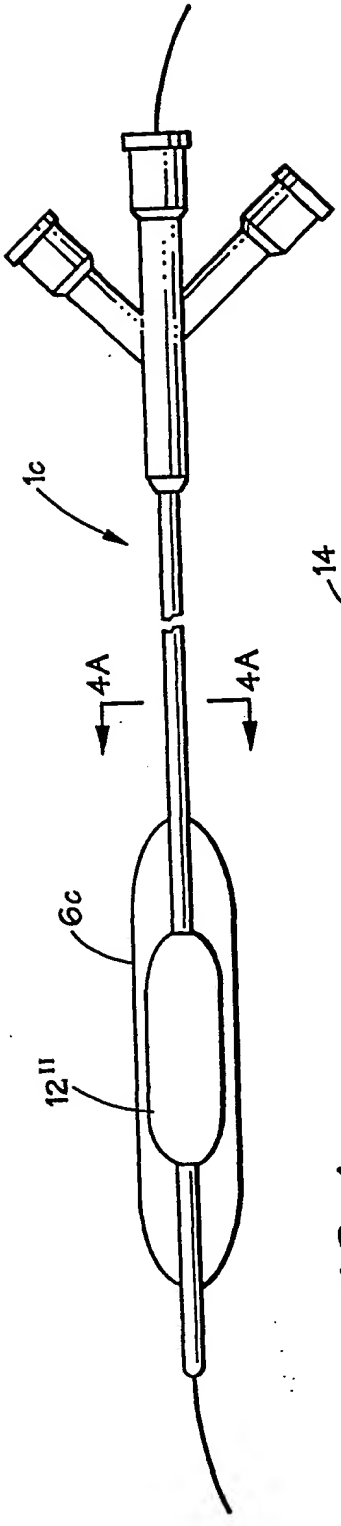

FIG. 4

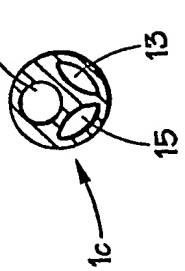

FIG. 4A

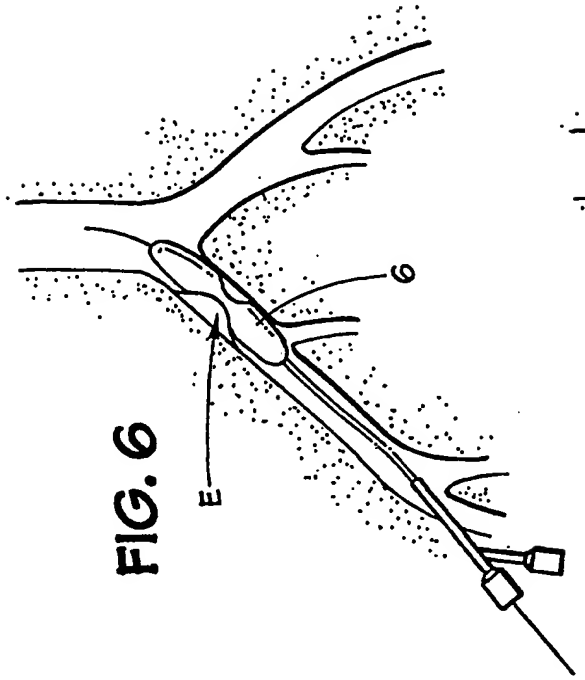

FIG. 6

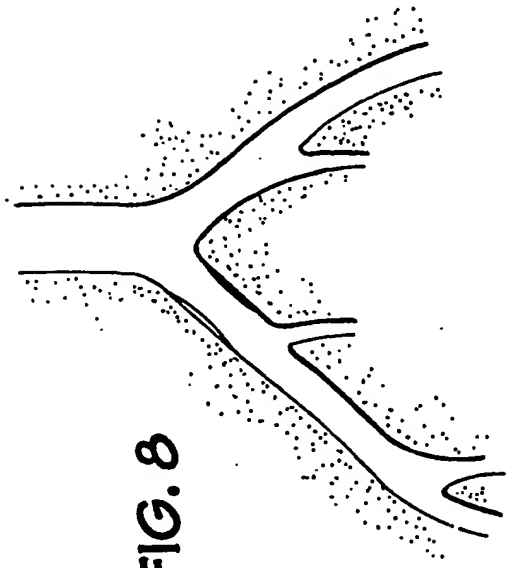

FIG. 8

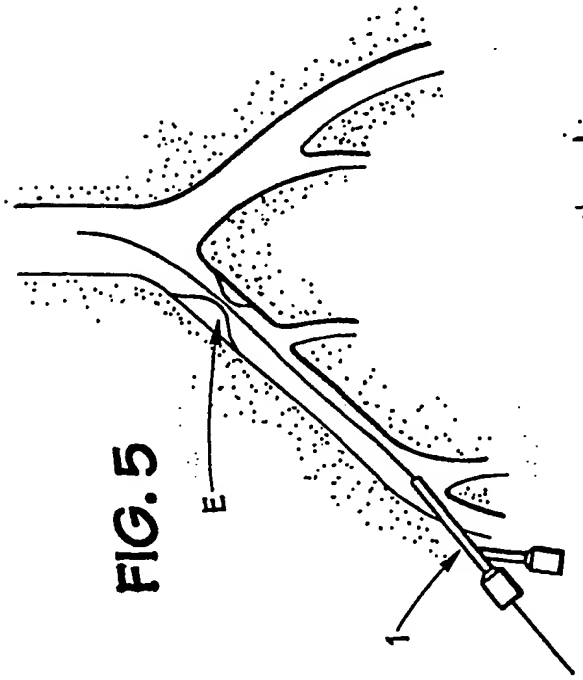

FIG. 5

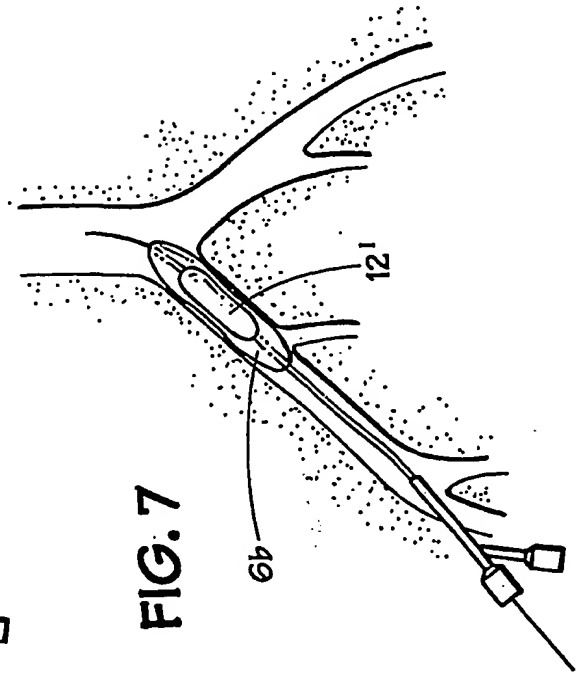

FIG. 7